

44. (Amended) A method of reducing the amount of nimesulide and or at least one pharmaceutically acceptable salt thereof required to treat a patient affected with pain comprising co-administering said nimesulide and/or at least one pharmaceutically acceptable salt thereof with an effective amount of oxycodone and/or at least one pharmaceutically acceptable salt thereof, to augment the analgesia attributable to said nimesulide and/or at least one pharmaceutically acceptable salt thereof during at least a portion of the dosage interval of said nimesulide and/or at least one pharmaceutically acceptable salt thereof.

45. (Amended) The pharmaceutical composition according to claim 30, wherein the oxycodone and/or at least one pharmaceutically acceptable salt thereof is present in an amount from about 2.5 mg to about 800 mg.

46. (Amended) The method of claim 38, wherein the oxycodone and/or at least one pharmaceutically acceptable salt thereof is present in an amount from about 2.5 mg to about 800 mg.

47. (Amended) The method of claim 38, wherein the ratio of oxycodone and/or at least one pharmaceutically acceptable salt thereof to nimesulide and/or at least one pharmaceutically acceptable salt thereof is from about 0.0001:1 to about 1:1.

#### **REMARKS**

Claims 30-47 are currently pending. Claims 30-32 and 35-47 have been amended. Support for these amended claims can be found throughout the specification, e.g., on page 8, line 27; page 12, line 19 to 22; page 13, line 15 to 19; and page 18 line 7 to 11. It is respectfully submitted that no new matter has been added by virtue of this amendment.

CONCLUSION

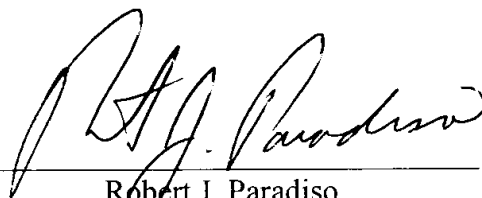
Applicants respectfully request that the amendments made be considered and made of record.

It is believed that no fee is due for the submission of this Preliminary Amendment. If any fees are deemed to be due, the Assistant Commissioner is hereby authorized to charge said fee to Deposit Account No. 50-0552.

An early and favorable decision is earnestly solicited.

Respectfully Submitted,  
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: \_\_\_\_\_



Robert J. Paradiso  
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
Tel. (212) 736-1940

**MARKED-UP VERSION TO SHOW CHANGE MADE****IN THE SPECIFICATION:**

Please amend the specification as follows:

At page 13, please amend the paragraph beginning at line 25 as follows:

- - Certain preferred COX-2 inhibitors include celecoxib (SC-58635), **[DUP-697] 5-bromo-s-(4-fluorophenyl)-3-[4-(methylsulfonyl)phenyl] thiophene (DUP-697)**, flosulide (CGP-28238), meloxicam, 6-methoxy-2 naphthylacetic acid (6-MNA), Vioxx (MK-966), nabumetone (prodrug for 6-MNA), nimesulide, **[NS-398] N-[2-(cyclohexyloxy)-4-nitrophenyl] methanesulfonamide (NS-398)**, **[SC-5766] 1-fluoro-4-[2-[4-methylsulfonyl]phenyl]-1-cyclopenten-1-yl] benzene (SC-5766)**, **[SC-58215] 5-(4-fluorophenyl)-1[4-(methylsulfonyl)phenyl]-3-trifluoromethyl 1H-pyrazole (SC-58215)**, **[T-614] N-[3-(formylamino)-4-oxo-6-phenoxy-4H-1-benzopyran-7-yl] methanesulfonamide (T-614)**; or combinations thereof. --

**IN THE CLAIMS:**

30. (Amended) A pharmaceutical composition comprising an analgesic combination consisting essentially of nimesulide **and/or at least one pharmaceutically acceptable salt thereof**; and oxycodone **and/or at least one pharmaceutically acceptable salt thereof**.

31. (Amended) The pharmaceutical composition according to claim 30, wherein the oxycodone **and/or at least one pharmaceutically acceptable salt thereof** would be subtherapeutic if administered without the nimesulide **and/or at least one pharmaceutically acceptable salt thereof**.

32. (Amended) The pharmaceutical composition according to claim 30, wherein the oxycodone and/or at least one pharmaceutically acceptable salt thereof; and nimesulide and/or at least one pharmaceutically acceptable salt thereof are administered orally, via implant, parenterally, sublingually, rectally, topically, or via inhalation.

35. (Amended) The pharmaceutical composition according to claim 30, wherein the ratio of oxycodone and/or at least one pharmaceutically acceptable salt thereof to nimesulide and/or at least one pharmaceutically acceptable salt thereof is from about 0.0001:1 to about 1:1.

36. (Amended) The pharmaceutical composition according to claim 30, wherein the nimesulide and/or at least one pharmaceutically acceptable salt thereof synergistically potentiates the effect of the oxycodone and/or at least one pharmaceutically acceptable salt thereof but the oxycodone and/or at least one pharmaceutically acceptable salt thereof does not synergistically potentiate the effect of the nimesulide and/or at least one pharmaceutically acceptable salt thereof.

37. (Amended) The pharmaceutical composition according to claim 34, wherein the oral solid dosage form includes a sustained release carrier which causes the sustained release of the nimesulide and/or at least one pharmaceutically acceptable salt thereof; the oxycodone and/or at least one pharmaceutically acceptable salt thereof; or both the oxycodone and/or at least one pharmaceutically acceptable salt thereof and the nimesulide and/or at least one pharmaceutically acceptable salt thereof when the dosage form contacts gastrointestinal fluid.

38. (Amended) A method of effectively treating pain in humans or other mammals, comprising administering to a patient an analgesic combination consisting essentially of nimesulide and/or at least one pharmaceutically acceptable salt thereof; and oxycodone and/or at least one pharmaceutically acceptable salt thereof such that the dosing interval of the nimesulide and/or at least one pharmaceutically acceptable salt thereof overlaps with the dosing interval of the oxycodone and/or at least one pharmaceutically acceptable salt thereof.

39. (Amended) The method of claim 38, wherein the nimesulide and/or at least one pharmaceutically acceptable salt thereof and the oxycodone and/or at least one pharmaceutically acceptable salt thereof are administered orally.

40. (Amended) The method of claim 38, wherein the nimesulide and/or at least one pharmaceutically acceptable salt thereof and the oxycodone and/or at least one pharmaceutically acceptable salt thereof are administered in a single oral dosage form.

41. (Amended) The method of claim 38, wherein the oxycodone and/or at least one pharmaceutically acceptable salt thereof would be sub-therapeutic if administered without the nimesulide and/or at least one pharmaceutically acceptable salt thereof.

42. (Amended) The method of claim 38, wherein the nimesulide and/or at least one pharmaceutically acceptable salt thereof is administered before, simultaneously with, or after administration of the oxycodone and/or at least one pharmaceutically acceptable salt thereof, such that the dosing interval of the nimesulide and/or at least one pharmaceutically acceptable salt thereof overlaps with the dosing interval of the oxycodone and/or at least one pharmaceutically acceptable salt thereof.

43. (Amended) A method of reducing the oxycodone and/or at least one pharmaceutically acceptable salt thereof required to treat a patient affected with pain, comprising co-administering said oxycodone and/or at least one pharmaceutically acceptable salt thereof with [said] nimesulide and/or at least one pharmaceutically acceptable salt thereof, to augment the analgesia attributable to said oxycodone and/or at least one pharmaceutically acceptable salt thereof during at least a portion of the dosage interval of said oxycodone and/or at least one pharmaceutically acceptable salt thereof.

44. (Amended) A method of reducing the amount of nimesulide and/or at least one pharmaceutically acceptable salt thereof required to treat a patient affected with pain comprising co-administering said nimesulide and/or at least one pharmaceutically acceptable salt thereof with an effective amount of oxycodone and/or at least one pharmaceutically acceptable salt thereof, to augment the analgesia attributable to said nimesulide and/or at least one pharmaceutically acceptable salt thereof during at least a portion of the dosage interval of said nimesulide and/or at least one pharmaceutically acceptable salt thereof.

45. (Amended) The pharmaceutical composition according to claim [1] 30, wherein the oxycodone and/or at least one pharmaceutically acceptable salt thereof is present in an amount from about 2.5 mg to about 800 mg.

46. (Amended) The method of claim 38, wherein the oxycodone and/or at least one pharmaceutically acceptable salt thereof is present in an amount from about 2.5 mg to about 800 mg.

47. (Amended) The method of claim 38, wherein the ratio of oxycodone and/or at least one pharmaceutically acceptable salt thereof to nimesulide and/or at least one pharmaceutically acceptable salt thereof is from about 0.0001:1 to about 1:1.